REMARKS/ARGUMENTS

In accordance with 37 CFR § 41.202(a), Applicant respectfully suggests that an interference be declared by the Director under 35 U.S.C. 135 between the instant application and pending U.S. Patent Application No. 10/783,136 of Robert Bessler, which was published on August 26, 2004 as U.S. Patent Appl. Publ. No. 2004/0167404 A1 (hereinafter "Bessler").

37 CFR § 41.202(a)(2)

Applicant has copied claims 1-7 of Bessler, incorporating them into the instant application as claims 7-13 by amendment. Thus, Applicant believes that claims 7-13 of the instant application interfere with claims 1-7 of Bessler.

Applicant proposes the following counts corresponding to claims of the instant application:

Count 1: The method of claim 7 of the instant application.

Count 2: The method of claim 8 of the instant application.

Count 3: The method of claim 9 of the instant application.

Count 4: The method of claim 10 of the instant application.

Count 5: The method of claim 11 of the instant application.

Count 6: The method of claim 12 of the instant application.

Count 7: The method of claim 13 of the instant application.

37 CFR § 41.202(a)(3)

Since applicant has copied claims 7-13 of the instant application from Bessler, the claims necessarily interfere, within the meaning of 37 CFR § 41.203(a), as follows:

Count 1: Claim 7 of the instant application interferes with claim 1 of Bessler because the claims are identical.

Count 2: Claim 8 of the instant application interferes with claim 2 of Bessler because the claims are identical.

Count 3: Claim 9 of the instant application interferes with claim 3 of Bessler because the claims are identical.

Count 4: Claim 10 of the instant application interferes with claim 4 of Bessler because the claims are identical.

Count 5: Claim 11 of the instant application interferes with claim 5 of Bessler because the claims are identical.

Count 6: Claim 12 of the instant application interferes with claim 6 of Bessler because the claims are identical.

Count 7: Claim 13 of the instant application interferes with claim 7 of Bessler because the claims are identical.

37 CFR § 41.202(a)(4)

Applicant respectfully submits that, for the following reasons, Applicant will prevail on priority.

The instant application claims priority of U.S. Provisional Patent Application Nos. 60/432,191, filed on December 6, 2002 and 60/442,869, filed on January 27, 2003. The Bessler application claims priority of U.S. Provisional Patent Application No. 60/448,611, filed on February 20, 2003, which is subsequent to the priority dates of the instant application. Thus, if an interference were declared as suggested herein, Applicant would be considered the senior party within the meaning of 37 CFR § 41.201.

Applicant submits that in or around March 2000, Biomec, the assignee of the present application, was contacted by Drs. Hazony and Katz from Case Western Reserve University to find an application for an ultrasound sensor. On or about March 29, 2000, a meeting was conducted between Dr. Robert Bessler and Biomec representatives, including Jan Lewandowski, to brainstorm possible applications of the ultrasound sensor. During the meeting, Dr. Robert Bessler indicated that a need existed for better detection of middle ear effusion. A discussion ensued regarding how to detect the presence of bacteria in the middle ear. It was determined that the bacteria itself was too small to be detected by the transducer alone. Accordingly, another discussion evolved regarding whether the presence of bacteria affected the properties of the fluid present in the middle ear.

Dr. Robert Bessler was paid in accordance to a 'Consulting Agreement' between Biomec and Dr. Robert Bessler signed on or about September 16, 1999 to attend and

participate in the meeting. A copy of the 'Consulting Agreement' is attached hereto as Exhibit A.

During March and April of 2000, research was conducted to determine the feasibility of developing the device proposed during the brainstorming meeting. During the research, phone conversations occurred between Jan Lewandowski and Dr. Bessler to discuss the findings. In particular, both Jan Lewandowski and Dr. Robert Bessler independently researched how bacteria affected fluid in the middle ear and both Jan Lewandowski and Dr. Robert Bessler independently discovered and discussed research findings that indicated a correlation between the viscosity of the fluid in the middle ear and the presence of middle ear effusion, or the presence of bacteria in the middle ear. It was known that fluid properties could be detected by ultrasonic technology; accordingly, it was determined that the ultrasound transducer was a potential product. A Phase I Ear Effusion SBIR grant was submitted on or about April 15, 2000.

In June 2000, Biomec and Bessler Innovative Technologies entered into an 'Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, and Commercialization', a copy of which is attached hereto as Exhibit B.

Biomec continued further development of the device and a Phase II Ear Effusion grant was submitted in August 2002. During this development, Jan Lewandowski, alone, discovered how to utilize the ultrasonic transducer technology to measure the fluid properties, and in particular, the viscosity, in the middle ear. Specifically, Jan Lewandowski discovered which portion of the received signal from the transducer to analyze and how to analyze such signal portions. Jan Lewandowski discovered that the amplitude of the received signals correlated to the viscosity of the fluid. Moreover, Jan Lewandowski discovered that utilizing the single transducer initially presented by Drs. Hazony and Katz was not applicable in a clinical setting due to the difficulties of 'aiming' the transducer in within the ear. Accordingly, Jan Lewandowski discovered that an array of transducers could be utilized to aim a plurality of signals at different locations in the ear. Jan Lewandowski also discovered that processing the transducer signals in a sequential order would show which transducer was responsible for each of the received signals. In December 2002, Biomec filed two provisional patent applications for: 1) a

curved array transducer design; and 2) a method for using the ultrasound technology to determine viscosity of middle ear fluid. Both provisional applications, as well as the present application, named both Dr. Rober Bessler and Jan Lewandowski as inventors.

37 CFR § 41.202(a)(5)

As shown in the tables below, each of the claims added by amendment herein are supported in the specification.

CLAIM 7	SPECIFICATION
"A diagnostic test for otitis media, comprising:"	Paragraphs [0010], [0031], [0032] and [0042] clearly state that the invention is provided for detecting ear disorders, and in particular, middle ear effusion. In the 'Background of the Invention' section, paragraph [0003] indicates that a common ear disorder is otitis media, which is characterized by the presence of middle ear effusion.
"detecting the presence [of middle ear effusion in a human patient] and"	Paragraph [0016] explains that a second echo of a transmitted signal, reflected by fluid in the middle ear cavity, will be received by the invention if effusion is present (see also paragraph [0014]).
"measuring the viscosity of middle ear effusion in a human patient; and"	Paragraph [0024] explains that an information analysis portion of the invention determines the viscosity of fluid within the ear.
"comparing the measured viscosity of the middle ear effusion in the human patient with at least three predetermined values for	Paragraph [0032] explains that the invention can distinguish three levels of fluid viscosity of fluid in the ear by

effusion viscosity,"	comparing measured values with experimental values.
"wherein such comparison provides information regarding the likelihood of presence of bacterial infection in the middle ear effusion in the human patient."	Paragraph [0024] also explains that the determined viscosity of the fluid in the ear is used to determine if an ear disorder exists. Paragraph [0003] explains, as background to the invention, that a common ear disorder is otitis media, which is characterized by the presence of middle ear effusion. It was known, at the time of the invention, in the field of ear disorders that the most common cause of otitis media is gram-negative bacteria.

CLAIM 8	SPECIFICATION
"The diagnostic test of claim 7"	See claim 7 above.
"wherein each of said predetermined values is based on a plurality of predetermined ranges of fluid viscosity measurements"	Paragraph [0032] explains that the invention can distinguish three levels of fluid viscosity of fluid in the ear by comparing measured values with experimental values. Paragraph [0034] explains how the experimental values were obtained for each range of viscosity.

CLAIM 9	SPECIFICATION
"The diagnostic test of claim 8"	See claim 7 above.
"wherein the predetermined ranges of fluid viscosity measurements are obtained from fluid viscosity measurements selected from the group consisting of middle ear	It was known at the time of the invention that a measured value of fluid viscosity obtained from a patient can be compared to data obtained from a sampling the general

effusions from the general human population,"	human population. In fact, this practice of comparing measured data with a data sample obtained from measuring others in the general human population is a common medical practice that has been in place for years prior to the filing of the subject application.
"middle ear effusions from a select population of human subjects, and"	It was also known at the time of the invention that the data taken from the general human population can be narrowed into a select population of human subjects, such as children 15 years old and younger. See paragraph [0003].
"simulated middle ear effusions from a model system, and"	Paragraph [0033] explains that artificial, or simulated, effusions can be prepared from procine stomach mucin dissolved in phosphate buffered saline and tested. Paragraph [0034] then explains that viscosities of the simulated effusions were measured and differentiated into the three levels of fluid viscosity (e.g., low, middle, high).
"wherein said comparing step comprises determining in which of said plurality of predetermined fluid viscosity ranges the human patient's middle ear effusion viscosity falls."	Paragraph [0032] explains that it can be distinguished whether the fluid in the ear is within one of the three levels of fluid viscosity.

CLAIM 10	SPECIFICATION
"A method for detecting in an animal the	Paragraph [0016] explains that a second

presence [of middle ear effusion by transmitting a signal into an ear canal of the animal] and"	echo of a transmitted signal, reflected by fluid in the middle ear cavity, will be received by the invention if effusion is present (see also paragraph [0014]). The specification of the instant application is directed towards detecting middle ear effusion in humans. It is known that humans are animals. See also Fig. 1.
"characterizing the viscosity of middle ear effusion by transmitting a signal into an ear canal of the animal,"	Paragraph [0012] explains that a probe is inserted into a canal of the ear. Paragraph [0013] explains that the probe includes a plurality of transducers. Paragraph [0014] explains that each transducer is able to transmit an ultrasonic signal into the ear. Paragraph [0024] explains that the signal information is used to provide a determination of viscosity of the fluid within the ear. See also Fig. 1.
"receiving a reflection of the signal, and"	Paragraph [0014] explains that each transducer receives the ultrasonic signal that is reflected back to the transducer.
"comparing the received signal with a standard comprising a range of signals obtained with fluids of varying viscosities,"	As explained in paragraph [0016], each reflected signal conveys information (e.g., data) concerning the surface from which the signal was reflected. For instance, the amplitude of the reflected signal can be used to predict a fluid state within a middle ear portion of the ear. As was known at the time of the invention, in order to determine how the amplitude compared with the

	viscosity present in the ear, the amplitude of the received signal is compared with a standard that was created by measuring a range of signals obtained with fluids of varying viscosities.
"wherein the range of signals are normalized to reflect a measurement of viscosity."	It was also known at the time of the invention, that the range of signals is normalized to take into account any outliers.

CLAIM 11	SPECIFICATION
"The method according to claim 10"	See claim 10 above.
"wherein at least one ultrasound transducer is used for signal transmission and reception."	Paragraph [0014] explains that each transducer is able to transmit and ultrasonic signal and is able to receive the ultrasonic signal that is reflected back to the transducer. Paragraph [0013] explains that any number of ultrasonic transducers can be utilized.

CLAIM 12	SPECIFICATION
"A method for determining if a human patient is a candidate for receiving antibiotic treatment,"	Paragraphs [0003] and [0004] explain that antibiotics are utilized in patients diagnosed with otitis media, which is characterized by the presence of middle ear effusion. Paragraph [0010] describes an apparatus for detecting the presence of an ear disorder, such as middle ear effusion, in a patient. Thus, if an ear disorder is detected, the patient is a candidate for

	antibiotic treatment.
"wherein the presence of middle ear effusion in the patient is detected and"	As stated above, Paragraph [0010] describes an apparatus for detecting the presence of an ear disorder, such as middle ear effusion, in a patient.
"the effusion viscosity is determined and"	Paragraph [0032] explains that the apparatus is used to determine the viscous state of fluid in an ear.
"[the effusion viscosity is] compared with at least one predetermined fluid viscosity value."	Paragraph [0032] also explains that the apparatus is able to distinguish whether the fluid in the ear is serous (thin), purulent (medium), or mucoid (thick).

CLAIM 13	SPECIFICATION
"The method of claim 12	See claim 12 above.
"wherein an ultrasound probe is used to detect [effusion viscosity] and"	Paragraph [0031] explains that an ultrasonic probe is interacted with the ear and the existence of an ear disorder is determined. Paragraph [0032] explains that the ultrasonic detection involves investigation of the viscous state of fluid in an ear.
"[wherein an ultrasound probe is used to] measure effusion viscosity."	Paragraph [0032] also explains that the apparatus is able to distinguish whether the fluid in the ear is serous (thin), purulent (medium), or mucoid (thick).

37 CFR § 41.202(a)(6)

As shown in the tables below, each of the counts were constructively reduced to practice by Applicant upon filing of U.S. Provisional Patent Application Nos. 60/432,191 on December 6, 2002 and 60/442,869 on January 27, 2003.

COUNT 1 (CLAIM 7)	
"A diagnostic test for otitis media, comprising:"	As disclosed in the 'Field of the Invention' section, the '869 application is directed to the detection of ear disorders. The 'Description of the Related Art' section of the '869 application, explains on p.1, ll. 7-10 that otitis media is an ear disorder characterized by the presence of middle ear effusion.
"detecting the presence [of middle ear effusion in a human patient] and"	P. 2, ll. 2-4 of the '869 application explains that middle ear effusion can be detected by analysis of ultrasonic signals and states that the middle ear effusion detection can be performed on a conscious patient.
"measuring the viscosity of middle ear effusion in a human patient; and"	P. 5, ll. 16-18 of the '869 application explains investigation of the viscous state of fluid in an ear.
"comparing the measured viscosity of the middle ear effusion in the human patient with at least three predetermined values for effusion viscosity,"	P. 5, ll. 18-20 of the '869 application explains distinguishing whether the fluid in the ear is serous (thin), purulent (medium), or mucoid (thick).
"wherein such comparison provides information regarding the likelihood of presence of bacterial infection in the middle ear effusion in the human patient."	P. 6, ll. 8-9 of the '869 application explains that the concentration of mucin is a significant factor determining viscosity of effusion. The 'Description of the Related

	Art' section of the '869 application, explains on p.1, ll. 7-10 that otitis media is an ear disorder characterized by the presence of middle ear effusion. It was known, at the time of the invention, in the field of ear disorders that the most common cause of otitis media is gram-negative bacteria.

COUNT 2 (CLAIM 8)	SPECIFICATION
"The diagnostic test of claim 7"	See count 1 (claim 7) above.
"wherein each of said predetermined values is based on a plurality of predetermined ranges of fluid viscosity measurements"	P. 6, ll. 1-6 of the '869 application explains that the invention can distinguish three levels of fluid viscosity of fluid in the ear by comparing measured values with experimental values. P. 6, ll. 13-19 of the '869 application disclose how the experimental values were obtained for each range of viscosity.

COUNT 3 (CLAIM 9)	SPECIFICATION
"The diagnostic test of claim 8"	See count 2 (claim 8) above.
"wherein the predetermined ranges of fluid viscosity measurements are obtained from fluid viscosity measurements selected from the group consisting of middle ear effusions from the general human population,"	It was known at the time of the invention that a measured value of fluid viscosity obtained from a patient can be compared to data obtained from a sampling the general human population. In fact, this practice of comparing measured data with a data sample obtained from measuring others in the general human population is a common

	medical practice that has been in place for years prior to the filing of the subject application.
"middle ear effusions from a select population of human subjects, and"	It was also known at the time of the invention that the data taken from the general human population can be narrowed into a select population of human subjects, such as children 15 years old and younger. See p. 1, ll. 7-9 of the '869 application.
"simulated middle ear effusions from a model system, and"	P. 6, ll. 8-12 of the '869 application explains that artificial, or simulated, effusions can be prepared from procine stomach mucin dissolved in phosphate buffered saline and tested. P. 6, ll. 13-15 then explains that viscosities of the simulated effusions were measured and differentiated into the three levels of fluid viscosity (e.g., low, middle, high).
"wherein said comparing step comprises determining in which of said plurality of predetermined fluid viscosity ranges the human patient's middle ear effusion viscosity falls."	P. 5, ll. 16-20 of the '869 application explains that it can be distinguished whether the fluid in the ear is within one of the three levels of fluid viscosity.

COUNT 4 (CLAIM 10)	SPECIFICATION
"A method for detecting in an animal the presence [of middle ear effusion by transmitting a signal into an ear canal of the animal] and"	P. 2, ll. 2-12 of the '869 application explains that a second echo of a transmitted signal, reflected by fluid in the middle ear cavity, will be received by the invention if effusion is present. The specification of the

	instant application is directed towards detecting middle ear effusion in humans. It is known that humans are animals. See also Fig. 1 of the '869 application.
"characterizing the viscosity of middle ear effusion by transmitting a signal into an ear canal of the animal,"	P. 3, ll. 1-3 of the '869 application explains that a probe is inserted into a canal of the ear. P. 3, ll. 4-5 of the '869 application explains that the probe includes a plurality of transducers. P. 3, ll. 7-13 of the '869 application explains that each transducer is able to transmit an ultrasonic signal into the ear. P. 6, ll. 1-9 of the '869 application explains that the pulse echo amplitudes can be used to fluid state (i.e., viscosity) of the ear. See also Fig. 1 of the '869 application.
"receiving a reflection of the signal, and"	P. 2, ll. 5-7 of the '869 application explains that the ultrasonic echo is the signal reflected back from the tympanic membrane.
"comparing the received signal with a standard comprising a range of signals obtained with fluids of varying viscosities,"	As explained in p. 4, ll. 17-20 of the '869 application, a signal analyzer is used to interpreted data received from the transducers. As was known at the time of the invention, in order to determine how the amplitude compared with the viscosity present in the ear, the amplitude of the received signal is compared with a standard that was created by measuring a range of signals obtained with fluids of varying viscosities.

"wherein the range of signals are normalized to reflect a measurement of viscosity."	It was also known at the time of the invention, that the range of signals is normalized to take into account any outliers.

COUNT 5 (CLAIM 11)	SPECIFICATION
"The method according to claim 10"	See count 4 (claim 10) above.
"wherein at least one ultrasound transducer is used for signal transmission and reception."	P. 3, ll. 1-15 of the '869 application explains that the transducers arranged on the probe can transmit and receive ultrasonic beams.

COUNT 6 (CLAIM 12)	SPECIFICATION
"A method for determining if a human patient is a candidate for receiving antibiotic treatment,"	P. 1, ll. 7-14 of the '869 application explains that antibiotics are utilized in patients diagnosed with otitis media, which is characterized by the presence of middle ear effusion. P. 2, ll. 2-12 of the '869 application describes an apparatus for detecting the presence of an ear disorder, such as middle ear effusion, in a patient. Thus, if an ear disorder is detected, the patient is a candidate for antibiotic treatment.
"wherein the presence of middle ear effusion in the patient is detected and"	As stated above, p. 2, ll. 2-12 of the '869 application describes an apparatus for detecting the presence of an ear disorder, such as middle ear effusion, in a patient.
"the effusion viscosity is determined and"	P. 6, ll. 1-9, 20-21 of the '869 application explains that effusion viscosity can be

	determined by analyzing the received pulse echo amplitudes.
"[the effusion viscosity is] compared with at least one predetermined fluid viscosity value."	P. 5, ll. 16-20 of the '869 application also explains that the apparatus is able to distinguish whether the fluid in the ear is serous (thin), purulent (medium), or mucoid (thick). P. 8, ll. 1-8 of the '869 application further explains that the amplitude of the received signal is related to the viscosity of the effusion within the middle ear and the level of viscosity is determined to indicate the treatment needed.

COUNT 7 (CLAIM 13)	SPECIFICATION
"The method of claim 12	See count 6 (claim 12) above.
"wherein an ultrasound probe is used to detect [effusion viscosity] and"	P. 3, ll. 1-15 of the '869 application explains that the transducers arranged on the probe can transmit and receive ultrasonic beams. P. 6, ll. 1-9 of the '869 application explains that the pulse echo amplitudes can be used to determine a fluid state (i.e., viscosity) of the ear. See also Fig. 1 of the '869 application.
"[wherein an ultrasound probe is used to] measure effusion viscosity."	As explained in p. 4, ll. 17-20 of the '869 application, the probe includes a signal analyzer is used to interpreted data received from the transducers. P. 5, ll. 16-20 of the '869 application also explains that the apparatus is able to distinguish whether the

	fluid in the ear is serous (thin), purulent (medium), or mucoid (thick).

Applicant has presented a prima facie case for priority, and respectfully request that an interference be declared between the subject application and U.S. Patent Application No. 10/783,136.

If there are any other fees required by this communication, please charge any such fees to our Deposit Account No. 16-1820, Order No. 34968US2.

Respectfully submitted,

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